

May 14, 2001

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Bernard A. Schwetz
Acting Principal Deputy Commissioner
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 01N-0078: Agency Information Collection Activities; Proposed Collections; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer Promotion of Prescription Drugs.

Dear Mr. Schwetz:

On behalf of Premier, Inc., a national strategic alliance of leading not-for-profit hospitals and health systems, we respectfully submit the following comments on the FDA's March 19, 2001 Federal Register notice, Agency Information Collection Activities; Proposed Collections; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer Promotion of Prescription Drugs.

Premier represents 210 owner health systems, the 954 hospitals and healthcare facilities they operate, and approximately 900 other hospital affiliates. Total annual purchasing volume for the alliance neared \$12 billion in 1999. Premier maintains major offices in Charlotte, NC; San Diego, CA; Chicago, IL; and Washington, DC.

Physician survey. As it is, the physician survey will yield a sufficient understanding of physicians' attitudes toward direct-to-consumer (DTC) advertising of prescription drugs. However, some additions or modifications to the survey might better capture other critical issues physicians have with such advertising. Suggested modifications are as follows:

- The intent of the survey appears to be the determination of the extent to which patients are asking physicians to prescribe (prescription) drugs based on advertisements they have been exposed to. This is an important determination to capture. However, a critical question not included in the survey is whether patients already receiving a specific drug therapy for a specific condition are asking their physicians to switch to the advertised drug. To determine the extent to which this is occurring, we suggest the addition of the following statement to question 22 of the physician survey: "The patient was already receiving a prescribed drug, other than the advertised drug, for their condition." Similarly, we suggest the addition of the following question to Section III, DTC Effects on Patient Outcomes: "Has led patients to want to use the more expensive advertised prescription drug rather than a less expensive prescription drug." (Agree strongly; Agree somewhat; Neither agree nor disagree; Disagree somewhat; Disagree strongly.)
- A possible outcome of DTC advertising is that the patient-physician relationship is jeopardized by the physician's response to the patient's request for the advertised medication. While some questions in the survey address this theoretical effect, we suggest the addition of the following questions to further characterize this potential outcome:
 - ➤ Between question 22 and question 23: "Not prescribing the advertised drug caused the patient to seek care from another physician." (yes/no)

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01N-0078

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- ➤ Between question 23 and question 30: "Not prescribing the advertised drug caused the patient to question my judgement." (Agree strongly; Agree somewhat; Neither agree nor disagree; Disagree somewhat; Disagree strongly.)
- Between question 23 and question 30: "Not prescribing the advertised drug caused the patient to feel he/she was being mistreated." (Agree strongly; Agree somewhat; Neither agree nor disagree; Disagree somewhat; Disagree strongly.)

Patient survey. As it is, the patient survey will yield a sufficient understanding of patients' attitudes toward DTC advertising of prescription drugs. However, the addition of the following statements/questions would make the patient survey consistent with the revised physician survey, as suggested above.

- Between question 29 and question 30: "If your physician did not prescribe the drug you asked for, did you go to another physician to get the advertised medication?" (yes/no)
- To the list of statements in question 30: "You were already taking a prescription drug for your condition."

Premier is appreciative of the opportunity to comment on this survey. For clarification or additional information, please contact Jeff Wojtynek, director, Clinical Pharmacy, at (630) 891-4716, or Margaret Reagan, director, Federal Affairs, at (202) 879-8003.

Sincerely,

Herb Kuhn Vice President

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